REMARKS

The following remarks are believed responsive to the points raised by the Office Action dated August 18, 2004. In view of these remarks, reconsideration is respectfully requested.

The Pending Claims

Claims 11, 14, and 23-30 have been canceled without prejudice, and claims 1-10, 12, 13, 15-22, and 31-34 remain pending. Claims 35-38 are added by this amendment.

Claims 1, 3, and 32 have been amended, and claims 35-38 have been added, to describe the invention more clearly. No new matter has been added, the basis for the amended claim language may be found within the original specification, claims and drawings.

Claims 1, 3, and 32 are supported at, for example, page 15, lines 4-6. Claims 35-38 are supported at, for example, page 15, lines 7-17. Entry of the above is respectfully requested.

The Office Action

Claims 1-13, 15-22, and 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent Application Publication No. 0,267,286 A1 to Nishimura et al. (hereinafter referred to as "Nishimura"), in view of European Patent Application Publication No. 0,630,675 A1 to Kuroki et al. (hereinafter referred to as "Kuroki") and U.S. Patent No. 5,547,576 to Onishi et al. (hereinafter referred to as "Onishi"). This rejection is respectfully traversed.

Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness in regard to the present invention. The present invention relates to a filter that *inter alia*, minimizes the passage of platelets therethrough. Nishimura emphasizes that the disclosed filter "hold[s] down the loss of platelets to a minimum" (page 6, lines 9-10), i.e., the filter allows platelets to pass therethrough. Thus, one would not be led from the platelet-passing filter of Nishimura to produce a filter that minimizes the passage of platelets therethrough. Additionally, Kuroki discloses a filter for separating leukocytes, and separating leukocytes and platelets, and Onishi discloses a filter for removing pathogenic substances (defined as leukocytes, <u>platelets</u>, and viruses) from a protein containing solution. One of ordinary skill in the art would not be led from the platelet-passing filter of Nishimura to the filter of Kuroki and the platelet-removing filter of Onishi.

The Advisory Action mailed November 10, 2004 states that the claims do not recite that the filter minimizes the passage of platelets therethrough. However, neither the Advisory Action, nor the Final Office Action, establishes a *prima facie* case of obviousness in regard to

the present invention. The Office Action and the Advisory Action merely list features from the cited references (relating to distinctly different filters for different applications) and conclude it would have been obvious to combine them to provide a single filter. Rather than providing a suggestion in the prior art, the Office Action has improperly used Applicants' disclosure as a template to select features from the cited references, and then used these features to fill in the gaps of the references. The Office Action does not provide the motivation leading one of ordinary skill in the art to combine these different features to provide the instantly claimed filter. This is impermissable hindsight, as the Federal Circuit has repeatedly held that a person of ordinary skill in the art must not only have had some motivation to combine the prior art teachings, but some motivation to combine the prior art teachings in the particular manner claimed. *In re Rouffet*, 149 F.3d, 1350, 1357, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

Moreover, the present independent claims (claims 1 and 32) recite that the filter elements have a negative zeta potential at physiological pH (formerly recited in dependent claim 14, now canceled). Dependent claim 12 recites elements with first and second predetermined Critical Wetting Surface Tensions (CWSTs), dependent claim 13 recites different predetermined CWSTs, and dependent claim 15 recites that at least one element has a CWST of at least about 90 dynes/cm. The Office Action, in rejecting claims 12-15, concluded the zeta potential and CWST would be similar for similar materials, but did not explain why this is so, and failed to explain what "similar" materials are.

These conclusions in the Office Action are not supported by the documents cited as the basis for the rejection, as evidenced in the attached Declaration under 37 CFR §1.132 by Brian T. Muellers, Ph.D.

Dr. Muellers has over 17 years of experience in the areas of blood filtration and filtration media, and has both a Ph.D. in Polymer Chemistry, and a M.S. in Chemistry, from Polytechnic University of New York. He is the sole author, or co-author, of at least 3 papers in reviewed Journals, relating to polymer technology, and is an inventor on nine U.S. Patents.

With respect to the conclusions in the Office Action regarding the zeta potential and the CWST, Dr. Muellers states "I believe, based upon my knowledge and experience, that these conclusions in the Office Action are incorrect" (Declaration, ¶7). Dr. Muellers, who reviewed Nishimura, Kuroki, and Onishi, explains the bases for his statement.

As an initial point, Dr. Muellers states that he does not believe Nishimura, Kuroki and Onishi provide sufficient information to determine the zeta potential, and furthermore, "[b]ased upon my knowledge and experience, to the extent that they provide information, they suggest elements with a positive zeta potential" (¶8).

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Moreover, as Dr. Muellers notes, Nishimura teaches using nitrogen-containing basic functional groups (see, page 9, lines 18-24), Kuroki teaches a cationic treatment (see, page 5, lines 13-14), and Onishi teaches immobilizing a polyamine compound (see, col. 5, line 59 through col. 7, line 11), and these will shift the zeta potential to the positive side due to the basic nature of the groups (¶¶ 9-11).

With respect to the CWST, Dr. Muellers states "I do not believe Nishimura, Kuroki and/or Onishi provide sufficient information to provide an element with a predetermined CWST, or two elements with different predetermined CWSTs, or elements with CWSTs of at least about 90 dynes/cm. There is no mention of CWST in any of Nishimura, Kuroki, and Onishi, and I am unable to determine the CWSTs of the elements disclosed in these 3 documents" (¶12).

Thus, for the reasons set out in Dr. Muellers' declaration, despite the conclusions stated in the Office Action, to the extent Nishimura, Kuroki and Onishi provide information with respect to the zeta potential, they suggest a positive zeta potential, rather than a negative zeta potential at physiological pH. Moreover, Dr. Muellers, who has 17 years of experience in the areas of blood filtration and filtration media, is unable to determine the CWSTs of the elements disclosed in these documents.

Accordingly, Applicants respectfully submit that even assuming arguendo one of skill in the art could be led from the teaching of Nishimura to that of Kuroki and even further to that of Onishi, the combinations would not lead one of ordinary skill in the art to the claimed invention.

With respect to newly added claims 35-38, since Nishimura, Kuroki and Onishi, to the extent they provide information regarding the zeta potential, suggest a positive zeta potential, the combination fails to lead one of ordinary skill in the art filter elements having negative zeta potentials (at physiological pH) in the range of from about -5 mv to about -20 mv, or in the range of from about -8 mv to about -20 mv, or from about -7 mv to about -15 mv.

With respect to claim 5, there is no suggestion in Nishimura, Kuroki and/or Onishi of the claimed alternating arrangement of elements. While the Office Action has repeatedly cited *In re Japikse*, 86 USPQ 70 (CCPA, 1950) and *In re Kuhle*, 188 USPQ 7 (CCPA, 1975) and referred to a "mere reversal of parts" and a "rearrangement of parts," those cases merely stand for the unremarkable proposition that the movement of a starting switch to a different position, and the particular placement of a electrical contact, are modifications known in a known process. For the reasons set forth above, the claimed invention is novel and non-obvious, and furthermore, interposing a fibrous filter element having a hydroxylated surface between two fibrous filter elements having surfaces including the nitrogen-to-oxygen ratio in the range of from at least

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0.01 to less than about 1.00 and having a negative zeta potential is not a modification known in the art. Applicants are entitled to submit separate claims encompassing separate arrangements of elements, and the Office Action has failed to establish a *prima facie* case of obviousness in regard to the claimed invention.

Conclusion

In view of the amendment and remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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